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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/624,946	<b>Applicant(s)</b> RAYMOND ET AL.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10,17-46 and 51-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,17-46 and 51-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

*SPD*

**Nonfinal Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 60-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into

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consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims contemplate the use of the claimed compounds in the treatment of solid tumours, AIDS, ischemia reperfusion injury and cardiac arrhythmias, respectively. The present specification discloses the compounds have (a) a protective effect on allergen induced inflammation or bronchoconstriction in the lung, (b) a protective effect on irritant induced edema on mouse ear, (c) an inhibitory effect on the release of mast cell contents and (d) an inhibitory effect on antigen-induced calcium flux. However, it lacks correlation between any of these properties and the treatment of solid tumours, AIDS, ischemia reperfusion injury or cardiac arrhythmias. Therefore, in order to practice the claimed invention, the skilled artisan would have to first search the prior art to find models useful for the determination of the effect of the claimed compounds in the treatment of all of the disorders encompassed by the instant claims. The skilled artisan would then have to test the effect of the claimed compound(s) in treatment of each disorder. The amount of experimental necessary to make said determination is undue because of the lack of guidance and/or working examples in the present specification.

4. Claims 1-10, 17-39, 41-46 and 51-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The court has held that an adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119, F.3d 1559, 1568 (Fed. Cir. 1997). The Federal Circuit has also adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 USC 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure...". *Enzo Biochem, Inc. v. Gen-Probe.*, 296 F.3d, 316, 1324-25 (Fed. Cir. 2002).

The present specification lacks an adequate description of the claimed subject matter because there is insufficient descriptive support for the term "prodrugs". The present specification lacks any correlation between said functional characteristic and any structure(s) and, thus, the skilled artisan would be unable to envision the compounds necessary for practice of the claimed invention. Thus, the claims fail to comply with the written description requirement.

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5. Claims 1-10, 17-39, 41-46 and 51-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite "prodrugs". However, the present specification does not provide the skilled artisan with a clear understanding of what is encompassed by said term. Therefore, the skilled artisan would be unable to determine the metes and bound of the claimed invention.

Claim 57 also recites "including but not limited to" which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

#### ***Double Patenting***

6. **The rejection of claims 47-50 under 35 USC 101 over claims of US Patent No. 6,638,629 is made moot by the cancellation of the instant claims.**

7. **The rejection of claims 1-10, 17, 18, 20-46 and 53-55 under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,638,629 is withdrawn.**

Note: The withdrawal is based on the filing of a terminal disclaimer.

8. **The provisional rejection of claim 52 under 35 USC 101 over claim 68 of copending Application No. 10/258,950 is maintained.**

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Note: The examiner notes applicant reserved the right to address this issue upon the issuance of the conflicting claim in the cited copending Application.

**9. The provisional rejection of claims 1-10, 17-46 and 53-63 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/258,950 is maintained.**

Note: The examiner notes applicant reserved the right to address this issue upon the issuance of the conflicting claims in the cited copending Application.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 2, 5-7, 28, 30, 33, 34, 36, 40-43 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Zasloff et al. (US 5,856,535).

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Zasloff et al. teach aminosterol esters having hydrogen or hydroxyl in the 6 and/or 7 positions (see the entire article, especially col. 2, line 1 – col. 10, line 68, see compounds such as #355, 356, 380, 394-396, 409-411, 431 and 432). The reference teaches various properties of the compounds such as its antimicrobial activity (see col. 46, Properties of the Aminosterol Esters). The compounds and compositions taught by the reference are encompassed by the instant claims.

It is noted, that a generic disclosure of the prior art directed to a recognizable small class of compounds having common properties which embrace the claimed compounds, is anticipatory notwithstanding the fact the claimed compounds are not specifically named. *In re Schaumann et al.* (CCPA 1978) 572 F2d 312, 197 USPQ 5; *In re Petering et al.* (CCPA 1962) 301 F2d 676, 133 USPQ 275.

12. Claims 1-7, 18, 36, 40, 41 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Burgoyne et al. (US 6,046,185).

Burgoyne et al. teach 3-oxime-6,7-bis(acetyloxy)-pregnan-3-one and its use in the preparation 6,7-oxygenated steroids (see col. 210, compound 357). The compound and composition taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 2, 5-7, 28, 30, 33, 34, 36, 40-43, 53, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zasloff et al. ('535).

Zasloff et al. teach aminosterol esters having a hydrogen or hydroxyl in the 6 and/or 7 positions (see the entire article, especially col. 2, line 1 – col. 10, line 68, see compounds such as #355, 356, 380, 394-396, 409-411, 431 and 432). The reference teaches various properties of the compounds such as antimicrobial activity (see col. 46, Properties of the Aminosterol Esters).

The instant claims differ from the reference by reciting compounds not exemplified by the reference, i.e., compounds having a hydroxyl group at both the C6 and C7 positions. However, the prior art teaches C6 and C7 can have one of two groups attached thereto. The reference also exemplifies hydroxyl at both the C6 and C7 positions. Based on the teachings of the prior art and the limited substituents at C6 and C7, the ordinary artisan in the art would readily envisage the exemplified prior art compounds having a hydroxyl group at both the C6 and C7 positions with the reasonable expectation that the compounds would be useful as taught by Zasloff et al.

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Claims 60 and 61 further differ from the reference by reciting the treatment of solid tumours and AIDS.

However, Zasloff et al. teach aminosterols are known to have anti-angiogenic properties and thus, useful in treatment of cancers and viral infections such as HIV. Thus, the skilled artisan would have the reasonable expectation that the aminosterols taught by Zasloff would be anti-angiogenic and, thus, useful in the treatment of solid tumours and AIDS as recited by the instant claims. The motivation would be based on the desire to obtain additional aminosterols useful in the treatment of cancers and viral infections as known in the art.


#### ***Telephone Inquiry***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
October 11, 2005